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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,079	09/26/2001	Robert S. Kieval	1071,1104101	2039
20350	7590	09/28/2004		
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			EXAMINER OROPEZA, FRANCES P	
			ART UNIT 3762	PAPER NUMBER

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/964,079	Applicant(s) KIEVAL ET AL.	
	Examiner Frances P. Oropeza	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/16/04 (Election).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 11-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 26-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/14/02; 4/24/02; 2/14/03; 8/25/03</u> <i>JFO</i> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/ Restriction

1. Claims 11-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on 4/16/04.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-10 and 27-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7-10 and 27-28, “the first output level” and “the second output level” lack antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-3, 5-9 and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Sjostrand et al. (US3650277). Sjostrand et al. teach a system for changing the baroreflex system using an activation device proximate a baroreceptor and electrically stimulating the site with a stimulation pattern containing two different levels of signals, an initial signal and subsequent signals, that vary according to amplitude, frequency or width (abstract; col. 1 @ 4-17, 46-53 and 62-65; col. 2 @ 1-32; col. 2 @ 59 – col. 3 @ 8; col. 3 @ 45-67; col. 3 @ 74 – col. 4 @ 31; col. 4 @ 64 – col. 5 @ 36; col. 7 @ 72 – col. 8 @ 4; col. 8 @ 40-58).

5. Claims 1-10 and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Obel et al. (US 5199428). Obel et al. teach a system for changing the baroreflex system using an activation device proximate a baroreceptor and electrically stimulating the site with a stimulation pattern containing two different levels of signals, an initial signal train and subsequent signal trains, that vary according to amplitude, frequency or width (figure 1; col. 2 @ 47-65; col. 3 @ 8-28; col. 3 @ 62 – col. 4 @ 20; col. 4 @ 42-45; col. 5 @ 45-51; col. 9 @ 9-25; col. 10 @ 9-13)

6. Claims 1, 5, 6 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Zabara (US 5540734). Zabara teaches a system for changing the baroreflex system using an activation device proximate a baroreceptor and electrically stimulating the site (figure 1; col. 2 @ 59-63; col. 4 @ 59-65; col. 7 @ 23-35; col. 8 @ 3-40).

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7. Claims 1, 5, 6 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Terry, Jr. et al. (US 5707400). Terry, Jr. et al. teach a system for changing the baroreflex system using an activation device proximate a baroreceptor and electrically stimulating the site (abstract; col. 1 @ 9-14; col. 2 @ 3-7, 13-21 and 50-60; col. 5 @ 22-40; col. 6 @ 50-64; col. 7 @ 15-34; col. 8 @ 15-58).

8. Claims 1-10 and 26-28 are rejected under 35 U.S.C. 102(e) as being anticipated by Kieval et al. (US 6073048). Kieval et al. teach a system for changing the baroreflex system using an activation device proximate a baroreceptor and electrically stimulating the site with a stimulation pattern containing levels of signals, optimized based on system feedback, the signals varying according to amplitude, frequency or width (abstract; figure 7; col. 1 @ 6-12; col. 1 @ 60 – col. 2 @ 23; col. 3 @ 32-46; col. 4 @ 10-14; col. 5 @ 7-38; col. 6 @ 6-11; col. 7 @ 10-46; col. 8 @ 3-28; col. 9 @ 46 – col. 10 @ 14).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

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evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 2-4, 7-10, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terry et al. (US 5707400) in view of Peters et al. (The Principle of Electrical Carotid Sinus Nerve Stimulation; A Nerve Pacemaker System for Angina Pectoris and Hypertension Therapy, Annals of Biomedical Engineering, Vol. 8, pp 445-458, 1980). As discussed in paragraph 7 of this action, Terry et al. discloses the claimed invention except for a two level stimulation system to attain and retain the beneficial impact of therapy.

Peters et al. teach carotid sinus nerve stimulation using a two level stimulation system for the purpose of attaining and retaining the beneficial impact of therapy. The need to optimize the treatment for each patient is highlighted, hence it would be obvious to modify the parameters of amplitude, pulse frequency, pulse width, and pulse bursts at different levels, and determine the most appropriate stimulation pattern based on routine experimentation. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used a two level stimulation system for the purpose of attaining and retaining the beneficial impact of therapy in the Terry, Jr. et al. system in order to use a proven feedback loop so the stimulation parameter and their patterns can be optimized (pages 445 and 451-454).

Specification

11. The specification is objected to because the Serial Numbers are missing the in Cross Reference section on page 1 of the specification.

Conclusion

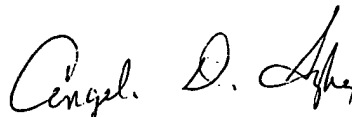
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frances P. Oropeza whose telephone number is (703) 605-4355. The examiner can normally be reached Monday through Friday from 9 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D. Sykes, can be reached on (703) 308-5181. The telephone number for facsimiles for regular communication and After Final communications is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

9/23/04
APO



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